

New, improved Kerraboot®: a tool for leg ulcer healing

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It is estimated that at any given time approximately 0.15% of the population will have an open ulcer (Callam et al, 1987; Cornwall et al, 1986) and that, overall, between 0.8% and 1.9% of the population will suffer from chronic lower limb ulcers at some point in their lives (Dale et al, 1983; Nelzen et al, 1996). Lower limb ulcers have many causes, with venous disease being the most common, accounting for 50–75% of all ulcers (Cornwall et al, 1986; Callam et al, 1987). Other causes include rheumatoid arthritis, diabetic peripheral neuropathy, arterial disease, trauma and malignancy.

According to the Department of Health, there are 1.3 million people in England living with diabetes (Department of Health and Diabetes UK, 2002). It is estimated that 15% of people with diabetes develop at least one foot ulcer during their life (Mancini and Ruotolo, 1997). Diabetic foot ulcers frequently lead to amputation and are associated with a high mortality.

The total annual cost to the NHS for treating diabetic peripheral neuropathy has been estimated to be in excess of £250 million, of which approximately 90% was attributable to the management of foot ulceration and almost 7% for amputations (Gordois et al, 2003). This is solely an estimate of the direct medical cost; there are likely to be substantial non-medical costs related to loss of productivity, not to mention intangible costs including stress, pain and anxiety. Although the financial cost of amputations is a small percentage of the total cost, the impact of an amputation on an individual's quality of life is very high. Effects of amputation on quality of life include limitation of daily activities, impairment of physical activity, depression, early retirement, reduced income, loss of social contacts and impairment of sexual activity (Levin, 2002). Such is the problem of amputations that the Saint Vincent Declaration set a goal of reducing by half all limb amputations for diabetic gangrene (World Health Organization and International Diabetes Federation, 1990).

Several factors lead to the high ulceration rates so frequently seen in patients with diabetes. These include diabetic neuropathy, poor vision, limited joint mobility and the consequences of cardiovascular and cerebrovascular disease (Jeffcoate and Harding, 2003). Factors related to the patient's environment—including trauma, abnormal stress, occupational hazards, social considerations and cigarette smoking—further contribute to the problem (Frykberg, 1999).

A common problem with lower limb ulcers is that they become chronic wounds that do not heal. Wound healing is

a dynamic pathway that progresses through distinct phases:

- ♦ Inflammation
- ♦ Proliferation
- ♦ Maturation.

This ultimately leads to the restoration of tissue integrity and function. Acute wounds usually heal within an expected time frame without complication (Lazarus et al, 1994). In non-healing or chronic wounds, the wound does not proceed through a timely, orderly sequence of healing (Lazarus et al, 1994). These wounds usually are the result of adverse underlying pathology.

The benefits of occlusive dressings and moist wound healing have been known and applied in clinical practice since Winter published his landmark study in 1962. Chronic wounds differ from acute wounds, in that they appear to be delayed or arrested in the early phases of wound healing, progressing slowly if at all. Not surprisingly, elements of chronic wound fluid have been shown to inhibit healing, specifically inhibiting proliferation of dermal fibroblasts and failing to stimulate the proliferation of microvascular endothelial cells and keratinocytes (Bucalo et al, 1993). Therefore, an occlusive dressing that promotes moist wound healing and yet removes chronic wound fluid (exudate) may confer additional benefits compared to standard dressings at promoting healing in chronic wounds.

Ulcer management

In treating ulcers, it is important to assess the health of the whole person and not to focus solely on the wound. Assessment of the patient's past medical history and presenting signs and symptoms, together with simple investigations

ABSTRACT

Lower limb ulcers can be debilitating to the individual affected, and are costly for the NHS to treat. The aim of treatment is to address the underlying pathology that caused the ulcer, and to create a warm, moist wound environment that promotes wound healing. This article discusses the improved Kerraboot®, which effectively draws excess moisture away from the wound, but also keeps the wound warm, moist and clean. Although evidence of cost-effectiveness has yet to be collected, anecdotal reports suggest that the device heals wounds quickly and reduces input from health professionals.

KEY WORDS

Leg ulcers ♦ Management ♦ Kerraboot®

Table 1. Some types and characteristics of treatment options for the management of lower limb ulcers

Category	Characteristics	Product examples
Films	Polyurethane based, semi-permeable, transparent and adhesive. Designed to enhance epithelial migration	OpSite®, Tegaderm™
Foams	Polyurethane based dressing capable of absorbing large volume of exudates	Allevyn™, Tielle®
Hydrogel dressings	Polymer designed to absorb and retain significant volumes of exudates	IntraSite® gel
Hydrocolloid dressings	Occlusive dressings designed to create and maintain a moist wound environment. Absorb low to moderate exudates	Comfeel, Duoderm, Tegaserb™ Thin
Alginate dressings	Highly absorbable biodegradable dressing derived from brown seaweed, suitable for heavily exuding wounds but may cause maceration of surrounding skin	Kaltostat®, Tegagen™, Sorbsan®
Bioactive dressings	Antimicrobial through release of iodine or silver into the wound	Iodosorb®, Aquacel® Ag, Acticoat®, Silvercel™
Biological skin substitutes	Provides rapid coverage of chronic wound. Thought to alter profile of cytokines within chronic wound. Available for epidermal, dermal and composite wounds.	Integra® (dermal; contains dermal fibroblasts and bovine collagen), Apligraf® (composite; contains newborn dermal fibroblasts in a bovine collagen matrix)
Autologous skin grafts	Uses a patient's own skin	N/A
Wound boot	Provides the optimum warm moist wound healing environment while allowing exudate to run from the wound where it is locked in the absorbent pad	Kerraboot®

should provide sufficient information to determine the aetiology of the ulcer. There are many influences that can affect the healing process, therefore it is vital the nurse assessing the ulcer has an understanding of these, so they can identify and modify these influences, so ensuring optimum healing of the wound. As with all wounds, early treatment choices might well determine the outcome in terms of healing rates, minimizing infection risk and functional and cosmetic outcomes (Dickerson et al, 1999).

To ensure correct and timely treatment is given, assessment of the wound bed itself will help to ascertain at what stage of healing the wound is. A vast array of dressings are available for the management of ulcers, and the characteristics of the most commonly used treatments are listed in *Table 1*. Healthy granulation tissue, which is red in colour, is an indication that the wound is now healing. If unhealthy granulation tissue is present, which is dark red and often bleeds, possibly indicating the presence of an infection, then the regime should be reviewed and changed as appropriate. Debridement may be necessary to remove foreign bodies and necrotic tissue.

Once the wound has healed, it is essential that recurrence of the ulcer is prevented. Because recurrence is so common with diabetic foot ulcers, prevention of new and recurrent ulcers is essential in the management of the diabetic foot. This is achievable through patient education in

foot care. Patients who understand the role they play are much more likely to comply with any instructions, such as the importance of wearing correct footwear. In a study by Edmonds et al (1986), patients who wore appropriate shoes had a recurrence rate of 26% compared to 83% of patients who chose to wear their own shoes. Reduction in the rates of ulceration of the foot will result in a reduction in amputation rates.

Kerraboot®

Kerraboot® is a novel boot-like dressing device indicated for moderate to heavily exuding, full and partial thickness wounds (*Figure 1*). It has been available in UK hospitals since November 2003 and achieved UK Drug Tariff listing in May 2004, allowing it to be prescribed in the community for the management of foot and leg ulcers.

Kerraboot® is described as an innovative, 'dual-action' wound-healing system specifically designed to allow drainage of wound exudate away from the wound bed and to lock it into the absorbent pad, while at the same time creating and maintaining the optimum moist, warm environment around the wound surface. It does not require any kind of secondary or retention dressings.

This year, 2006, a new version of Kerraboot® was launched which has been designed with a super-absorbent pad specifically for use in the community. The exudate



Figure 1. Kerraboot® ‘clear’.

forms a soft gel which conforms to the shape of the foot, offering enhanced comfort. The result is a dressing that requires changing less frequently, yet still locks away odour and facilitates healing. Kerraboot® is a transparent dressing that allows easy inspection of the wound by health care professionals. An opaque version, Kerraboot® ‘white’, will be available on prescription from 1 July 2006 (Figure 2). This may be more suited for patients in the community, among other people.

In a pilot study using a prototype boot in hospital, both patients and nurses commented that application of the boot was easy (Barker et al, 2001). Odour was eliminated entirely. Doctors were able to see the wound without nurses taking down the dressing, saving up to 2 hours per round. Further, self-application was made possible by the ease with which the boot was applied.

Following the success of the pilot study, a second study was performed with Kerraboot® that assessed the ease of use and acceptability of this device (Leigh et al, 2004). Patients found it to be comfortable and convenient to wear, with 85% reporting that it was better or much better than their previous dressings, and with odour being almost entirely eliminated. Health-care professionals confirmed the ease of application and removal and most rated it as better than dressings used previously.

Finally a direct comparison was performed of the acceptability of Kerraboot® compared to standard treatment (Allevyn™) for the management of diabetic foot ulcers (Edmonds et al, 2006). Key findings included:

- ♦ A dramatic reduction in time to change the dressing was noted with Kerraboot®
- ♦ Self-application being greater with Kerraboot®
- ♦ Reduced ulcer-related odour

- ♦ Similar healing rates, but increased granulation tissue with Kerraboot® compared to Allevyn™.

Overall, the authors concluded that Kerraboot® resulted in less health-care resource use than standard treatment.

In addition to these studies, several case studies have been published that have highlighted the role of Kerraboot® in effectively managing lower limb ulcers, often preventing the need for amputation (Barker and Leigh, 2005; Butterly and Wilson, 2005). That it manages exudates, eliminates odour and is deemed comfortable by the patient with less pain at dressing changes compared to previous treatment, resulting in improved patient concordance, has further been confirmed (Davies, 2005; Wilson, 2006). Kerraboot® has also been successfully reported to prepare non-healing ulcers for skin grafting (Barker et al, 2005). The ease of application and removal allows it to be applied either by the patient or by a relative, so allowing the patient to self-manage treatment at home. This can improve the quality of life of the patient and reduce the burden on the health-care system (Barker and Leigh, 2005).

Cost-effectiveness of Kerraboot® is extremely difficult to measure, as it must take into account nursing time, length of hospital stay in addition to the costs of the dressings used. However, in a direct comparison of dressings only (i.e. excluding nursing time), Butterly and Wilson determined that the cost differential between Kerraboot® and a hydrogel/hydrofoam regime was negligible (Butterly and Wilson, 2005).



Figure 2. Kerraboot® ‘white’ will be available on FP10 from 1 July 2006.

‘Kerraboot® has been shown to facilitate the healing of new, recurrent and long-duration foot and leg ulcers and is an important addition to the armamentarium of wound healing dressings and devices.’

Walker discusses the use of Kerraboot® in an older patient with chronic non-healing ulcers, 18 in total, of four years’ duration, during which time the patient had been admitted to hospital five times (Walker, 2006). Management

of the ulcers with Kerraboot® facilitated a rapid healing outcome, such that Walker concluded it was highly cost-effective.

How and when to use Kerraboot®

Kerraboot® is indicated for moderate to heavily exuding, full and partial thickness wounds. It is designed to treat necrotic, sloughy and dull wounds by draining away the harmful substances found in chronic wound exudate. By debriding and cleaning the wound it prepares the wound bed for healing. Clinical evidence suggests that development of healthy granulation tissue may be visible within 14 days of treatment. Treatment of the ulcer with Kerraboot® may be continued until the wound has healed.

Conclusion

An enormous variety of dressings are currently available for the management of lower limb ulcers which all too often results in prescribing confusion. Yet despite this, there is still a significant unmet need for effective treatment. Kerraboot® has been designed to address this unmet need, and there is growing clinical evidence to support the use of it for chronic wounds of more than 4 weeks’ duration.

Kerraboot® effectively modifies the wound environment and manages exudate. This not only eliminates odour but also avoids ‘strikethrough’, which in other

dressings may provide a portal for infection. The ability to apply and remove the dressing without causing pain to the patient is clearly an important feature of Kerraboot® both for the patient, who may be able to self-manage, and for the health-care worker, who spends less time dressing the wound. There is evidence to suggest that it is a cost-effective treatment of chronic ulcers, however no cost-effectiveness study has yet been performed.

In conclusion, Kerraboot® has been shown to facilitate the healing of new, recurrent and long-duration foot and leg ulcers and is an important addition to the armamentarium of wound healing dressings and devices for the management of this debilitating condition. **BJCN**

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KEY POINTS

- ♦ Lower limb ulcers commonly become chronic wounds and fail to heal.
- ♦ Assessing the health of the whole person is essential in the treatment of ulcers.
- ♦ Kerraboot® facilitates healing by removing exudate from the wound and locking it away while still maintaining a warm, moist environment.
- ♦ Clinical data suggests Kerraboot® is as effective as standard dressings, manages exudates, controls odour, reduces time for dressing changes and is suitable for self-application saving valuable health care resources.
- ♦ Kerraboot® will shortly be available in an opaque ‘white’ version as well as the transparent ‘clear’ version.